April 2005

Nevada State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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www.state.nv.us/pharmacy

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Schedule of 2005 Board Meetings

April 13-14 ..... Las Vegas
June 1-2 ..... Reno
July 20-21 ..... Las Vegas
September 7-8 ..... Reno
October 26-27 ..... Las Vegas
December 7-8 ..... Reno

New Board Member Appointed by the Governor's Office

Leo D. Basch, PharmD, has been appointed to the Nevada State Board of Pharmacy by Governor Kenny C. Guinn. Pharmacist Basch fills the vacancy of Marci Ranick, whose employment promotion took her out of Nevada. Like his predecessor, Leo works for Walgreens Company and is a resident of Las Vegas.

Leo received his PharmD degree from Idaho State University College of Pharmacy in 1995. Dr Basch shares an uncommon circumstance with Board Member Dave Wuest, namely that both are married to practicing pharmacists. Leo's wife Janet is also an employee in a Walgreens pharmacy.

Legislature in Session

The 2005 Session of the Nevada Legislature began in February. The Board of Pharmacy did not submit a bill draft this session, but a number of bill draft requests were identified that addressed pharmacy-related issues. There may be bills to:

- Add a representative of a manufacturer or wholesaler to the Board, which would increase the number of the Board members to eight and would increase the number of members needed to constitute a quorum to five members.
- Require certain drug wholesalers to be fingerprinted, have background checks, and post a bond or other form of security as well as other requirements. The bill also provides criminal penalties for failure to comply with certain requirements.
- Require drug manufacturers and wholesalers to report annually the purpose of any gift, fee, payment, subsidy or other economic benefit provided to a practitioner, pharmacist, or administrator of a health care facility. Failure to comply would be penalized by a fine of not more than $10,000.
- Establish a Web site that would enable Nevada's patients to have their prescriptions dispensed by Canadian pharmacies.

It can be expected that there may be other bills that may address the cost of prescription drugs, which is viewed as a "hot button" topic with consumers and many legislators.

Flip-Flop Stop

Prescribing practitioners and pharmacists have become accustomed to the post-dating of prescriptions for Schedule II (CII) controlled substances. Patients have enjoyed the benefit provided by a multiple month regimen of drug. Particularly in intractable pain maintenance as well as Attention Deficit Hyperactivity Disorder patients, an extended period of supply alleviated the need for patients to pay monthly visits to their physician for little more than receiving another CII prescription. Practitioners experienced the same benefit – avoiding the interruption of busy schedules to write a maintenance order that could have been for a longer period of time.

The legal authority of post-dating CII prescriptions was not found in 21 CFR 1306, but had been written in guidelines published by Drug Enforcement Administration (DEA). The guidelines provided that a practitioner could have additional written instructions on the prescription such as, "Do not fill until (date)" or "Do not fill before (date)," or similar language.

Many Nevada physicians had expressed the desire for Nevada to adopt the same language wherein Nevada law, absent of such authority, prevented the federal interpretation to be used. The Board of Pharmacy's bill in the 2003 Legislative Session contained a provision allowing what DEA seemed to be allowing, namely that practitioners could write post-dated CII prescriptions. The new Nevada law became effective October 1, 2003.

Within the last few months, DEA withdrew the guidelines and the CII prescribing with post-dating was described as tantamount to refilling the CII prescription and, correspondingly, was prohibited by law. The Nevada law is still in existence.

The Board of Pharmacy notified approximately 6,500 prescribing practitioners that federal law superceded state law

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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regarding CII prescriptions and accordingly to discontinue the post-dating of controlled substance prescriptions. The notice should have reached all practitioners by March 1, 2005.

If a pharmacy receives a prescription that was issued by the practitioner before the March 1 date, and that prescription was post-dated to be filled after that date, the Board of Pharmacy office will not consider this a compliance violation. Prescriptions issued after March 1 may not contain post-dating language and should not be filled.

Controlled Substance Abuse Prevention Task Force

The Board of Pharmacy continues its involvement in the Nevada Prescription Controlled Substance Abuse Prevention Task Force. This program has been very successful and has been stated by some to be the "gold standard" in the nation for controlled substance prescription monitoring programs. In fact, the program was mentioned in the National Drug Control Strategy presented by the White House to Congress in 2004.

In a recent meeting of the American Medical Association, Nevada's success was noted in the following statement: "The Nevada program was unique when created and continues to provide a valuable collaborating opportunity between health professionals, state licensing and regulatory agencies and law enforcement to proactively address prescription drug abuse."

In August 2004 a new development increased the accessibility for physicians and pharmacists. A secure Web center now allows practitioners with passwords to request drug utilization reports. This access can provide the requesting practitioner with a rapid response of 10 or 15 minutes in most instances or at a minimum same-day responses during weekday working hours. The information is available off-line to prevent inappropriate access. While the secure Web center access is growing in popularity, the majority of the over 20,000 report requests per year sent to physicians and pharmacists are prepared and returned manually.

A second unique feature of the program includes an intervention officer. For persons who have been acknowledged to have doctor shopped and/or committed prescription fraud through physicians and pharmacies for an extended period of time, an invitation is given to have an interview with the intervention officer. The patient may bring his or her attorney, priest or minister, family members, and others to understand his or her options. Pain management with one doctor or one pharmacy, addiction treatment, or law enforcement proceedings are offered. Of course, the criminal justice component has not yet been selected. Over 45 individuals have had their lives improved; several have expressed thanks for the intervention and the program.

Several states are implementing controlled substance prescription monitoring programs in the United States and the federal government has provided financial assistance for their establishment. The process constructively engages practitioners, pharmacies, and treatment programs without extensive and costly law enforcement involvement.

Special Note

The *Nevada State Board of Pharmacy News* is considered one of the Board's official methods of notification to pharmacies and pharmacists. They have been and will continue to be used in hearings as proof of notification. It is important to read the *Newsletters* carefully and to retain them for future reference.

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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